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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,290	11/28/2001	Thomas Terwee	10806-154	4031

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EXAMINER	
LANDREM, KAMRIN R	
ART UNIT	PAPER NUMBER
3738	8

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

Office Action Summary	Application No.	Applicant(s)	
	09/996,290	TERWEE ET AL.	
	Examiner	Art Unit	
	Kamrin R. Landrem	3738	

-- The MAILING DATE of this communicati n appears on th c ver sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 33-75 is/are pending in the application.

4a) Of the above claim(s) 40,51-54,58,59 and 72 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 33-39,41-50,55-57,60-71 and 73-75 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: Please elect **one** of the following device embodiments: **A, B, C**.

Species A: Figures 1a and 1b

Species B: Figure 2

Species C: Figure 3

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none of the claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Holly C. Kozlowski on June 17,2003 a provisional election was made with traverse to prosecute the invention of Species A, Figures 1a and 1b, claims 34-51 and 55-75. Affirmation of this election must be made by applicant in replying to this Office action. Claims 52-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 40, 51, 58, 59, and 72 have also been withdrawn by the examiner as being directed to non-elected Species II because they set forth the limitations of a plug provided with a cut and a roughened contacting means which are not found in the elected species.

Claims 34-39,41-50,55-57, and 60-71 and 73-75 are hereby considered for examination purposes.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

Claims 36 and 41 are objected to because of the following informalities:

In claim 36, it is unclear what applicant is claiming when referring to or comparing to when reciting "a largest diameter".

In claim 41, the phrase "the amount aberrations of a wavefront" is awkwardly worded. It is recommended that claim be amended to read --the amount *of* aberrations--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is indefinite because it depends from a cancelled claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

> international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33, 44-50, 55-57, 60-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Tahi et al (USPN6,358,279 B1).

With reference to Figures 2 and 3, Tahi discloses a sealing device 100 adapted to compensate for aberration comprising a transparent disc-shaped flexible plug 110 made of a deformable silicon polymer (5: 30-51) having a slightly larger area than the incision adapted to seal a capsulorhexis of a capsular bag. The sealing device further comprises an anteriorly protruding adjusting means 112 that is removable at fastening point 140 (Figure 1b) and admits an injection device 118 for injecting a liquid material (7:46) capable of preventing epithelial cell growth (7:34-36). Upon removal of the delivery means 118 the plug 110 retains a sealed position thereby preventing the displacement of lens forming liquid from the capsular bag. (6:1-14). The flexible anteriorly protruding (8:37-38) adjusting means 112 is removed after injection of lens forming material (9:4-9). The plug member can be positioned in a rhexis of more than 1mm in diameter (8:4-6) and can remain in the capsular bag after lens formation (5:53-55) or can likewise be removed after lens formation (7:54-55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-39 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tahi et al.

Tahi, as discussed supra, discloses the method of positioning a sealing device 100 comprising a flexible plug 110 and removable adjusting means 112 wherein the adjusting means is located so that the peripheral anterior surface of plug 110 contacts the inner posterior wall (7:4-7) to seal a capsulorhexis opening creating during ocular surgery. Tahi does not specifically recite that the injection of the lens forming material exerts sufficient pressure on posterior side of plug to seal the excised area. It is inherent that the filling of the capsular bag would increase the volume of the capsular bag and thereby create a pressure that would exert force against the wall of the capsular bag. This pressure would thereby result in the sealing device being compressed against the interior wall of the capsular bag and thereby strengthen the seal to prevent leakage of the lens material. If not inherent, it therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to inject an amount of lens forming material that would result in increased pressure and create an enhanced sealing between the plug and the inner posterior wall of the capsular bag.

Claims 41-43 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tahi as applied to claims 34,44, and 68 and above, and further in view of Werblin (USPN 6,413,276).

Tahi, as discussed surpa, discloses the method and sealing device as claimed. Tahi does not disclose the method of measuring the cornea and the amount of aberrations to select a sealing device to compensate for these aberrations. Werblin teaches the method of measuring the aberrations of the eye and using this data to create a surface to correct for the

aberrations/abnormalities on the eye or a customized optical element, such as an intraocular lens (7:1-10). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the step of measuring the amount of the aberrations of the eye as taught by Werblin to before inserting a sealing device 100 as disclosed by Tahi to insure that the device comprises a surface that is capable of compensating and correcting aberrations and abnormalities.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-3905 for regular communications and 703-308-3905 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kamrin Landrem
Examiner
AU 3738

KRL
July 8, 2003

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
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